K003222

NOV - 3 2000

10. Premarket Notification 510(k) Safety and Effectiveness Summary

HERMES™ Operating Room Control Center 510(k) Summary

Computer Motion, Inc. is submitting the following safety and effectiveness summary.

1) Submitter Information:

Computer Motion
130-B Cremona Drive
Goleta, CA 93117

Contact: David U. Thomas, Regulatory Affairs Specialist
Phone: (805) 968-9600 Ext. 214
FAX (805) 685-9277
Prepared: October 13, 2000

2) Name of Device:

Proprietary Name: HERMES™ Operating Room Control Center
Common Name is HERMES™
Classification Name: Laparoscope for Use in General and Plastic Surgery, Regulation Number 876.1500, Class II.

3) Substantially equivalent to the HERMES™ OR Control Center (K973700) and the more recent 510(k) K991444 for HERMES control of the AESOP®3000HR

4) The HERMES Operating Room Control Center is a computer-driven system whose basic function offers the surgeon the additional voice control option for selection of attachment device parameter settings.

The intent of the HERMES OR Control Center is to allow for simplified and more direct control of medical device settings by the physician, thereby eliminating the necessity of using the various interfaces existing on the Stryker Endoscopy 882 Camera, Stryker Quantum 5000 Light Source, Stryker SE5 Shaver, WOM 20L Insufflator, W.O.M. 2.0L Arthroscopy Pump, Stryker Total Performance System, Berchtold Surgical Lights, Steris Amsco Table Model SP3085, AESOP®HR (HERMES-Ready) and Valleylab Force FX™ Electro-surgical Unit in the Operating setting, or relying upon verbal communications between the surgeon and other personnel in the operation room in order to adjust surgical equipment.

The HERMES OR Control Center is indicated for use with Stryker Endoscopy 882 Camera, Stryker Quantum 5000 Light Source, Stryker SE5 Shaver, WOM 20L Insufflator, WOM 2.0L Arthroscopy Pump , Stryker Total Performance System, Berchtold Surgical Lights, Steris Amsco Table Model SP3085, AESOP®HR (HERMES-Ready) and Valleylab Force FX™ Electro-surgical Unit. It can be used in

general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy where a laparoscope/endoscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization in indicated and examination of the evacuated cardiac chamber

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Mr. David U. Thomas
Regulatory Affairs Specialist
Computer Motion, Inc.
130 Cremona Drive, Suite B
Goleta, California 93117

Re: K003222
Trade Name: Modification to Hermes Operating Room Control Center
Regulatory Class: II
Product Code: GCJ
Dated: October 13, 2000
Received: October 16, 2000

Dear Mr. Thomas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K003222

DEVICE NAME: HERMES™ with Valleylab Force FX™

INDICATIONS FOR USE:

The HERMES OR Control Center is indicated for use with Stryker Endoscopy 882 Camera, Stryker Quantum 5000 Light Source, Stryker SE5 Shaver, W.O.M. 20L Insufflator, W.O.M. 2.0L Arthroscopy Pump, the Stryker Total Performance System, Berchtold Surgical Lights, Steris Amsco Table Model SP3085, AESOP®HR (HERMES-Ready), and Valleylab Force FX™ Electro-surgical Unit. It can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy where a laparoscope/endoscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization in indicated and examination of the evacuated cardiac chamber during performance of valve replacement. The users of the HERMES ORCC are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003222